



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,338	08/07/2001	James Tobin	22058-516-DIV-CON	3551

30623 7590 04/21/2005

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY
AND POPEO, P.C.
ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER

MERTZ, PREMA MARIA

ART UNIT PAPER NUMBER

1646

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/924,338

Applicant(s)

TOBIN, JAMES

Examiner

Prema M. Mertz

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 39-53 and 55-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 39-53, 55-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1646

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/14/2005 has been entered.
2. Claims 1-17, 19-38, 54 have been canceled previously. Claims 39-42, 52-53, 55-57, 59, 62-65 and amended claims 18, 43-51, 58, 60-61 (3/14/2005) are under consideration.
3. Receipt of applicant's arguments and amendments filed on 3/14/2005 is acknowledged.
4. Applicant's arguments filed on 3/14/2005 have been fully considered but were non-persuasive. The issues remaining and new issues are stated below.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 18, 39-53, 55-62 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims embrace an antibody as it occurs *in vivo*. However, since it would that applicants do not intend to claim a naturally occurring product, such as an antibody circulating in

Art Unit: 1646

an animal, amending the claim to require the hand-of-man i.e. isolated antibody, would obviate this rejection.

Claim Rejections - 35 USC § 112, first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7a. Claims 18, 58, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 18 and 28, recite “an epitope in” which language is new matter in the claims, since the instant specification fails to disclose such a limitation. The specification fails to provide proper support for this language in the claims for the following reason:

In the specification, page 23, lines 5-11, teach using the entire human IL-11R as an immunogen, or by using fragments of human IL-11R, such as the soluble mature human IL-11R.

The specification does not disclose the specific limitation of “an epitope in” as recited in the claims. This rejection can only be obviated by reciting the specific language for which there is support in the instant specification.

7b. Claims 18, 39-53, 55-65 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

Art Unit: 1646

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is maintained for reasons of record set forth at pages 2-3 of the previous Office action (9/26/03) and pages 2-3 of the previous Office action (4/14/04).

Applicant argues that the claims have been amended to specify that the antibody binds to “an epitope” within a human IL-11 receptor polypeptide and claims 18, 58 and 62 have been amended to recite that the recited antibody specifically reacts with a human IL-11 receptor protein. Furthermore, Applicant argues that the claims further require that the human IL-11R protein “comprises” an amino acid sequence from SEQ ID NO:2 selected from the group consisting of amino acids 26 to 111, amino acids 112 to 365, amino acids 366 to 390, and amino acids 391 to 422. Thus, Applicant argues that the presently claimed antibody expressly excludes antibodies that bind to a polypeptide or moiety other than an IL-11 Receptor polypeptide. However, contrary to Applicants arguments, the claims fail to expressly exclude antibodies that bind to a polypeptide or moiety other than an IL-11 receptor polypeptide. Claim 18, for example, still recites “wherein said IL-11R protein comprises.....” and the recitation of the limitation “comprises” permits the instant claims to encompass an antibody which binds to an epitope that is not contained within SEQ ID NO:2. It was well known in the art long before the instant invention was made to express a recombinant protein as part of a fusion protein “comprising” in addition to the amino acid sequence of a desired protein, an antigenic tail such as a FLAG epitope, a polyhistidine tail, keyhole limpet hemocyanin or a protein A fragment to facilitate the purification of the desired protein, as disclosed on page 23, lines 5-17, of the instant specification. The text on page 23 of the instant specification encompasses a human IL-11R

Art Unit: 1646

polypeptide, which can include a “tag” (hapten). Therefore, because of the presence of the term “comprises” in the instant claims, the claims encompass any antibody which can bind to any epitope which can be expressed as a portion of a polypeptide comprising the amino acid sequence as set forth in SEQ ID NO:2 and, therefore they essentially encompass any antibody which can bind to any polypeptide or protein comprising a “tag”. The instant specification, however, does not provide the guidance needed to produce an antibody, which binds to any epitope other than an epitope which is contained within SEQ ID NO:2 of the instant application.

Claim Rejections - 35 USC § 102

8. Claims 18, 39-53, 55-65 are rejected under 35 U.S.C. § 102(b) as being anticipated by the Giaever patent (4,054,646).

This rejection is maintained for reasons of record set forth at page 3 of the previous Office action (9/26/03) and pages 3-4 of the previous Office action (4/14/04).

Applicant argues that independent claims 18, 58, and 62 have been amended to require that the recited antibody specifically reacts with “an epitope” in a human IL-11R protein and that since Giaever does not describe antibodies to an IL- 11R protein, therefore, it fails to describe all the features of the invention now claimed. Applicants also argue that Gievaer additionally fails to disclose an antibody that binds to polypeptides that include the recited amino acid sequences, i.e. an amino acid sequence from SEQ ID NO:2 selected from the group consisting of amino acids 26 to 111, amino acids 112 to 365, amino acids 366 to 390, and amino acids 391 to 422.

However, contrary to Applicants arguments, Giaever still describes the invention now claimed, and anticipates the instant claims because the claims recite, “comprises an amino acid sequence”, which claims encompass an antibody to any hapten or tag, including the KLH tag, which was

Art Unit: 1646

bound by the antibody of Giaever prior to the time of the instant invention. The reference discloses the KLH antibody (column 18, lines 5-13) meeting the limitations of claims 18, 39-53, 55-65. Therefore, the KLH antibody of the reference anticipates instant claims 18, 39-53, 55-65.

Conclusion

No claim is allowable.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
April 8, 2005